

510(k) SUMMARY

Company Name: Omega Medical Imaging, Inc
Address: 675 Hickman Circle
Sanford, FL 32771
Telephone No: 407-323-9400
Registration No.: 1052701
Contact person: James A. Princehorn
Date Prepared: 14 April 2006
Device (trade) name: e-VIEW radiographic/fluoroscopy system
Classification Name: Angiographic X-ray System
Classification Panel: Radiology
CFR Section: 892.1650 and 892.1600
Device Class: Class II
Device Code: DWB & JAA
Common/usual name: System, X-Ray, Fluoroscopic, Image-Intensified

OCT 20 2006

Predicate device(s):

- Siemens AXIOM ARTIS U Angiography System (K040675)
- Philips Integris H5000 Angiography System (K984545)
- Omega Medical Imaging B200/C300 Fluoroscopy System (K902005).

Device description:

- The Omega Medical Imaging, Inc. e-VIEW systems are comprised of an x-ray source/image receptor positioning device in a permanently floor mounted C-Arm configuration. The positioning of the source/receptor is achieved by motorized motions controlled by the operator. The patient table can be configured with different motorized motions including elevating, Trendelenburg and vertical tilt, lateral and longitudinal table top travel, and lateral table top tilt. The imaging is achieved by way of an image intensifier/CCD camera with digital image processing.

Intended use:

- The Omega Medical Imaging, Inc. e-VIEW systems are intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.

Safety Information:

- The Omega *e*-VIEW systems will comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31, and 21 CFR 1020.32.
- The Omega *e*-VIEW systems will comply with the international safety standards IEC 60601-1, IEC 60101-1-2, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, and IEC 60601-2-32 .
- The Omega *e*-VIEW systems will comply with UL 60601-1 and CAN/USA C22.2 No.601.1-M90

Conclusion:

The Omega *e*-VIEW systems do not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Omega considers the *e*-VIEW systems to be substantially equivalent with the predicate devices.



FEB 19 2013

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. James A. Princehorn
President
Omega Medical Imaging, Inc.
675 Hickman Circle
SANFORD FL 32771

Re: K062647
Trade/Device Name: e-VIEW Fluoroscopy System Model CS-50
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: August 31, 2006
Received: August 6, 2006

Dear Mr. Princehorn:

This letter corrects our substantially equivalent letter of October 20, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

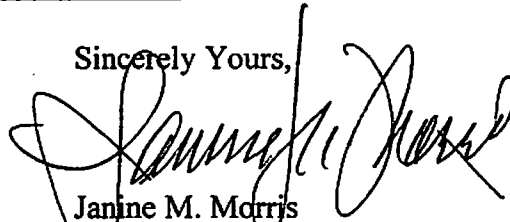
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read 'Janine M. Morris', is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number: K 062647

Device Name: e-VIEW Fluoroscopy System, Model CS-50

Indications For Use:

The Omega Medical Imaging, Inc. e-VIEW systems are intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

David A. Sigman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062647